

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----X	
AZUR PHARMA, INC.,	:
	:
Plaintiff,	:
	:
v.	:
	:
TRIGEN LABORATORIES, INC.,	:
	:
Defendant.	:
-----X	

No. 10 Civ. 207 (NRB)

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR A PRELIMINARY INJUNCTION**

**COHEN TAUBER SPIEVACK & WAGNER P.C.
420 Lexington Avenue, 24th Floor
New York, New York 10170
(212) 586-5800**

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Stephen Wagner
Leo L. Esses
Cohen Tauber Spievack & Wagner P.C.
420 Lexington Avenue, 24th Floor
New York, NY 10170
(212) 586-5800
Fax: (212) 586-5095
swagner@ctswlaw.com
lesses@ctswlaw.com

Counsel to Plaintiff Azur Pharma, Inc.

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INTRODUCTION

Plaintiff Azur Pharma, Inc. ("Azur") respectfully submits this memorandum of law in support of its application for a preliminary injunction (i) enjoining and restraining defendant Trigen Laboratories, Inc. ("Trigen" or "Defendant"), its officers, agents, servants, employees, and any persons in active concert or participation with them, from falsely marketing, promoting, advertising, offering for sale, selling, transferring, transporting, distributing or otherwise moving or disposing its pre-natal vitamins that it currently distributes under the trade names Taron EC Calcium ("Taron"), Taron EC Calcium DHA ("Taron DHA") and Folivane-EC Calcium DHA ("Folivane," together with Taron and Taron DHA, the "Trigen Products") to physicians, pharmacies, patients, wholesalers, retailers, chains, distributors, mail order houses or independent pharmacies, (ii) requiring Defendant, its officers, agents, servants, employees, and

any persons in active concert or participation with them, to immediately recall all of the Trigen Products from all physicians, pharmacies, wholesalers, retailers, chains, distributors, mail order houses, and independent pharmacies, and (iii) granting such other and further relief as this Court deems just and proper.

PRELIMINARY STATEMENT

This is a classic case of one company leaching on to the accomplishments of another for its own benefit. As shown below and in the supporting documentation submitted herewith, Azur came up with a concept, spent the money turning a concept into product, advertised, marketed, and succeeded. Trigen, seeing Azur's success, falsely informed the market that its product was equivalent to Azur's. As shown below, this is not the case, and an injunction is more than warranted.

As set forth in the Amended Complaint¹, Azur is a private pharmaceutical company focused on health products related to the central nervous system, women's health, and urological issues. In and around October of 2008, Azur began producing, advertising and selling Gesticare®, Gesticare® with DHA and, in 2009, Gesticare® with DHA DR (the "Gesticare® Products").

The Gesticare® Products are multi-vitamin supplements for use by pregnant women. Included in the vitamin supplements are iron and calcium. As set forth in the accompanying Declaration of Michael Kelly, dated March 10, 2010 ("Kelly Decl."), the presence of iron inhibits absorption of calcium when the two elements are released in the body together. The Gesticare® Products were formulated to address this specific issue of "competition" for absorption of iron and calcium. Thus, the Gesticare® Products utilize proprietary and patent

¹ Attached as exhibits to the Declaration of Stephen Wagner, dated March 10, 2010 (Wagner Decl.) are the (i) Complaint, at Exhibit A, (ii) Answer, at Exhibit B, and (iii) Amended Complaint, at Exhibit C.

pending bi-phasic technology, which enables the patient to take one tablet that includes both calcium and iron, whereby there is an immediate release of iron into the bloodstream, and a delayed, subsequent, calcium release. This allows the body to first absorb the full compliment of iron and then, after its delayed release, the full compliment of calcium.²

On or about September 1, 2009, Azur learned that Trigen intended to compete with Azur and market its own pre-natal vitamins as low cost alternatives to the Gesticare® Products. Azur also learned that Defendant intended to market and advertise its pre-natal vitamins as utilizing bi-phasic technology. Azur sought, and only recently obtained, samples of Taron DHA and Folivane to determine whether they are, or are not, bi-phasic. As set forth in the accompanying declarations, testing of Taron DHA and Folivane³ proved that they are not bi-phasic.

Moreover, as set forth in the Declarations of Feridoon Bakhshi, dated March 9, 2010 (“Bakhshi Decl.”) and John Reuther, dated March 10, 2010 (“Reuther Decl.”), and the Kelly Declaration, Trigen also misrepresents that its products have the same level of ingredients as the Gesticare® Products. Indeed, as set forth in the Bakhshi Declaration, laboratory testing and analysis of the Taron DHA and Folivane products has proved that the quantity/amount of several ingredients significantly differ from those of Defendant’s own product labels and package inserts, and also differ from the quantity/amounts in Gesticare® with DHA and Gesticare® with DHA DR.

In addition, as set forth in the Reuther Declaration, laboratory analysis revealed that the Taron DHA and Folivane red gelatin DHA capsules contain only approximately 216 mg of DHA (Taron DHA) and 222.4 (Folivane) approximately between 13.3% and 11%, respectively, fewer

² As set forth in the Kelly Declaration, Azur’s significant investment in the Gesticare® Products has led to those products’ recognition by physicians as a leading bi-phasic pre-natal vitamin.

³ No samples of Taron were available for testing.

than the 250 mg Defendant has represented that they contain on the product packages, and both also contain significant amounts of Eicosapentaenoic Acid (EPA), which is not reflected on the packages. EPA is not present in any significant amounts in the Gesticare® Products.

Because of Defendant's false labeling, marketing and advertising of its pre-natal vitamin as bi-phasic and containing ingredients identical to the Gesticare® Products, the drug data publishing services, which provide, among others, doctors and pharmacies with lists of generic drugs, inaccurately consider Defendant's pre-natal vitamins as generic to the Gesticare® Products. This is because the drug data publishing services rely on the information provided to them by the drug maker and do not conduct any independent evaluation.⁴

As a result of Defendant's false representations and the confusion that exists now and will continue to grow, an immediate injunction is required to ensure that Trigen ceases to market its products falsely as an alternative to the Gesticare® Products when, in fact, they are not.

STATEMENT OF FACTS

The facts relevant to this motion are set forth in the accompanying (i) Kelly Declaration; (ii) Wagner Declaration; (iii) Reuther Declaration; and (iv) Bakhshi Declaration, submitted herewith, which are incorporated by reference.

ARGUMENT

A. Azur is Entitled to Injunctive Relief

It is well-settled in this Circuit that a plaintiff is entitled to a preliminary injunction upon showing (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits to make them a fair ground for litigation, and a balance of hardships tipping decidedly in the moving party's favor; and (2) the threat of irreparable harm. *Tom Doherty*

⁴ This fact is not in dispute - - Trigen admitted this in its answer to the Complaint (Wagner Decl. Ex. B).

Associates, Inc. v. Saban Entertainment, Inc., 60 F.3d 27 (2d Cir 1995); *Louis Vuitton Malletier v. Burlington Coat Factory Warehouse Corp.*, 426 F.3d 532, 537 (2d Cir. 2005).

As demonstrated below, Azur is likely to succeed on the merits, as the scientific evidence demonstrates that Defendant is falsely representing the capabilities and ingredients of its products in order to appear as a generic to the Gesticare® Products. Alternatively, there are sufficient “serious questions” going to the merits concerning Trigen’s claims that its products are both bi-phasic and have the same ingredients as the Gesticare® Products to make them fair ground for litigation. Either way, so long as Defendant continues to misrepresent its drugs, Azur is and will continue to suffer irreparable harm if an injunction is not immediately granted.

B. Azur Has Met the Test for Injunctive Relief

Azur can show both the likelihood of success on the merits and irreparable harm. It also meets the alternative test for a balance of hardships tipping decidedly in favor of Azur. *Church of Scientology Int’l v. Elmira Mission of the Church of Scientology*, 794 F.2d 38 (2d Cir. 1986).

1. Azur is Likely to Succeed on the Merits

Azur is likely to succeed on the merits of its Lanham Act claim because Defendant’s claim that Taron DHA and Folivane are bi-phasic is “literally” false as a factual matter. A test of the Trigen Products prove conclusively that they are not bi-phasic. Bakhshi Decl. ¶¶ 13 - 27; Exs. C - G *Johnson & Johnson-Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992). Further, Defendant’s claims that the Trigen Products contain the identical ingredients and ingredient strengths as the Gesticare® Products are also false. Bakhshi Decl. ¶¶ 28 – 36; Exs. A – B, I - K; Reuther Decl. ¶¶ 8 – 22.

Accordingly, Azur is likely to succeed on the merits of its claims.

2. Absent the Injunction, Azur will Suffer Irreparable Harm

Defendant is falsely advertising, marketing and selling the Trigen Products as having the exact same ingredients and bi-phasic technology as the Gesticare® Products. Trigen makes these representations on its product packages and in its statements to drug-publishing services for listing of its products on those services' data bases. Bakhshi Decl. ¶¶ 28 – 36, Exs. A – B, I – K; Reuther Decl. ¶¶ 8 – 22, Exs. A - E. This has already caused the drug publishing services to rate the Trigen Products as equivalents of the Gesticare® Products. Kelly Decl. ¶¶ 29 - 31. Thus, Azur already is suffering irreparable harm. *Time Warner Cable, Inc. v. DirecTV, Inc.*, 497 F.3d 144, 148 (2d Cir. 2007). Defendant's false representations will not only cause Azur to lose sales and marketing opportunities, but Azur will suffer loss of the goodwill of patients, physicians, pharmacists and other participants in the marketplace for prescription drugs. Kelly Decl. ¶¶ 45 - 49. Moreover, Defendant's improper false representations will dilute and limit the distinctiveness of the Gesticare® Products. Indeed, Defendant already admits that at least one of the drug data publishing services has identified the Trigen Products as alternatives to the Gesticare® Products and that such identification "may lead to numerous formularies and pharmacy systems listing Taron and Folivane as substitutable products to Gesticare® Products." Wagner Decl. at Ex. B, ¶ 27.

Furthermore, Azur will be irreparably injured if an injunction is not issued because it will be extremely difficult for Azur to calculate lost sales resulting from Defendant's improper conduct. *Zeneca, Inc. v. Eli Lilly & Co.*, 1999 U.S. Dist LEXIS 10852, at *113 (S.D.N.Y. Jul. 19, 1999) ("[t]he likelihood of customer confusion, impairment of plaintiff's reputation and good will and probable diversion of customers, combined with difficulty of proving actual monetary damages arising from Lanham Act injuries, justifies a presumption of irreparable injury once the violation has been established") (citing *Upjohn Co. v. Am. Home Prods. Corp.*, 598 F. Supp 550, 555 (S.D.N.Y.

1984)). By its own admission, Defendant's false representations will cause the consumer to be confused and thus the consumer will not know that the product they have purchased is not legitimately a generic of the Gesticare® Products. Wagner Decl., Ex. B, ¶¶ 26, 27, 29 & 32. This further exacerbates the normally difficult problem of proving lost sales due to infringement or false advertising and furnishes an independent ground for a finding of irreparable harm. *See McNeil Labs., Inc. v. Am. Home Prods. Corp.*, 416 F. Supp 804, 809 (D.N.J. 1976) ("nor would it be a simple matter to calculate in damages the value of the customers who would be forever lost to [the plaintiff's product] were we to permit [defendant] to continue to market [its infringing product]").

3. A Balance of the Hardships Favors Azur

The balance of the hardships tips decidedly in favor of Azur who has suffered and will continue to suffer irreparable harm from Defendant's literally false advertising and marketing claims. Kelly Decl. ¶¶ 45 - 49. Defendant cannot be heard to complain of any hardship when its infringement must come to an end. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696 (D.N.J. 2000). Moreover, by this motion, Azur does not seek to preclude competition by others against the Gesticare® Products, but rather is seeking to protect itself from Defendant's false statements of technology and ingredients that are made unfairly to cannibalize and trade on the reputation and efforts of Azur and its products, affecting not only Azur, but also pregnant women and their unborn fetuses. Kelly Decl. ¶ 49. In this case, denial of immediate injunctive relief will harm Azur and the public far more than Defendant. Azur has been marketing and selling its Gesticare® Products for more than one year, and Gesticare® has become synonymous with providing pregnant women with, among other things, iron and calcium nutrients, through bi-phasic technology, beneficial to a healthy pregnancy. Kelly Decl. ¶¶ 5 - 12. Azur has expended significant money in promoting the Gesticare® Products. Kelly Decl. ¶ 9. In stark contrast,

Defendant is only now beginning to introduce the Trigen Products, and doing so with knowing and intentional false representations specifically to confuse the public regarding the purported similarity between the Trigen Products and Gesticare® Products. It is Defendant that makes false statements about the technology and ingredients of its products. It is Defendant who has chosen to falsely market, advertise and sell its pre-natal vitamins. Stated another way, no harm can possibly come to Defendant that Defendant has not brought upon itself. Thus, the balance of hardships tips decidedly in Azur's favor.

C. An Injunction is in the Public Interest

The public has a profound interest in truthful marketing, advertising and selling by drug companies. Consumers should not have to worry that they are being prescribed a specific drug from a doctor and then not receive the proper medication because a company misleads the public into believing that its product is a generic for another. Indeed, by falsely representing that its product is bi-phasic, Defendant is lulling physicians into thinking that prescribing the Trigen Products will provide their pregnant patients with the full compliment of iron and calcium. However, by taking the Trigen Products, the pregnant women are clearly not getting these necessary nutrients in the preferred amounts. The consumer, as well as Azur, requires the protection of this Court.

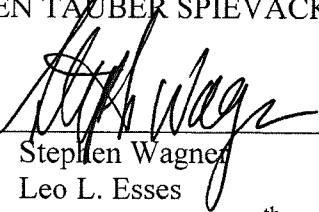
CONCLUSION

For the reasons stated above, Azur respectfully requests that the Court grant its motion and provide such other and further relief as this Court deems just and proper.

Dated: New York, New York
March 11, 2010

Respectfully submitted,

COHEN TAUBER SPIEVACK & WAGNER P.C.

By: 

Stephen Wagner
Leo L. Esses
420 Lexington Avenue, 24th Fl.
New York, NY 10170
(212) 586-5800
swagner@ctswlaw.com
lesses@ctswlaw.com